

JUN 8 - 2005

K050916

Special 510(k): Device Modification  
Safe-Cross® RF TO Crossing System [Peripheral]

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## **510(K) SUMMARY**

### **SUBMITTER INFORMATION**

- A. Company Name: IntraLuminal Therapeutics, Inc.  
B. Company Address: 6354 Corte Del Abeto – Suite A  
Carlsbad, CA 92009  
C. Company Phone: (760) 918-1820  
D. Company Facsimile: (760) 603-9615  
E. Contact Person: Pamela Misajon  
Vice President of Regulatory Affairs and Quality Assurance

### **DEVICE IDENTIFICATION**

- A. Device Trade Name: Safe-Cross® Radio Frequency Total Occlusion Crossing System  
B. Device Common Name: Catheter Guide Wire  
C. Classification Name: Catheter Guide Wire  
D. Device Class: Class II (per 21 CFR 870.1330)

### **IDENTIFICATION OF PREDICATE DEVICE**

The predicate device is the Safe-Cross Radio Frequency Total Occlusion Crossing System, manufactured by IntraLuminal Therapeutics and cleared under Premarket Notification 510(k) K040037.

### **DEVICE DESCRIPTION**

The Safe-Cross Radio Frequency Total Occlusion Crossing System consists of the following:

- 0.014" Safe-Cross RF Crossing Wire – Straight and Angled Tip (with Torquer and Tip Shaping Tool) (275cm Working Length)
- 0.014" Safe-Cross RF Crossing Wire – Straight and Angled Tip (with Torquer and Tip Shaping Tool) (175cm Working Length)
- 0.018" Safe-Cross RF Crossing Wire – Straight and Angled Tip (with Torquer and Tip Shaping Tool) (275cm Working Length)

- 0.035" Safe-Cross RF Crossing Wire – Straight and Angled Tip (with Torquer) (275cm Working Length)
- Safe-Cross RF System Console with Display and Footswitch

The modified Safe-Cross RF System is similar to the predicate Safe-Cross System. The proximal end of the RF Crossing Wire is connected to a Y-Site hub that houses the optic fiber connector and the RF connector. The optical connector is connected to the OCR input on the console to allow the medical practitioner to visualize structures within the vessel for navigation purposes. The RF connector is connected to the RF output on the console. This allows the medical practitioner to provide discrete RF energy to the distal tip to assist in moving the wire tip through the occlusion in the vessel.

The RF Crossing Wire is packaged in a Tyvek® sealed plastic tray with the Tip Shaping Tool. A Torquer is provided in a separate peel pouch. The packaged RF Crossing Wire is provided "STERILE" (ethylene oxide) and non-pyrogenic, and is intended for single use only.

## **INTENDED USE**

The Safe-Cross® Radio Frequency Total Occlusion Crossing System is indicated for use in facilitating the placement of devices used in percutaneous interventions in native peripheral arteries with total occlusions. The device is not to be used in the carotid arteries.

## **TECHNOLOGICAL CHARACTERISTICS**

The components of the Safe-Cross System are similar in basic materials, design, construction and performance to the predicate device. The RF Crossing Wires have been modified to improve performance characteristics (i.e., tip flexibility, tip shaping and shape retention). The safety and performance of the modified Safe-Cross System has been verified through biocompatibility testing, bench testing and *in vivo* animal studies.

## **BIOCOMPATIBILITY AND PERFORMANCE DATA**

Biocompatibility testing has been conducted to verify that the materials in the modified 0.014" RF Crossing Wires are safe. *In vitro* bench testing was conducted to evaluate the performance characteristics of the modified RF Crossing Wires. Benchtop performance test results indicate that the modified RF Crossing Wires satisfy safety and performance requirements of the device specifications and do not raise additional safety issues. *In vivo* animal studies have shown that the components of the system function properly together and satisfy intravascular performance requirements in an animal model.

## **CONCLUSIONS DRAWN FROM STUDIES**

On the basis of the testing conducted on the modified Safe-Cross System it may be concluded that the device satisfies safety and performance requirements when used in accordance with the Instructions for Use for the indicated patient population. The modified Safe-Cross System is substantially equivalent to the predicate device.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

Intraluminal Therapeutics, Inc.  
c/o Ms. Pamela Misajon  
Vice President of Regulatory Affairs and Quality Assurance  
6354 Corte del Abeto, Suite A  
Carlsbad, CA 92009

SEP 18 2013

Re: K050916

Trade/Device Name: Safe-Cross Radio Frequency Total Occlusion Crossing System  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II  
Product Code: PDU  
Dated: May 5, 2005  
Received: May 9, 2005

Dear Ms. Misajon:

This letter corrects our substantially equivalent letter of June 8, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must


comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



 Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K050916

Device Name: Safe-Cross® Radio Frequency Total Occlusion Crossing System

Indications For Use: The Safe-Cross® Radio Frequency Total Occlusion Crossing System is indicated for use in facilitating the placement of devices used in percutaneous interventions in native peripheral arteries with total occlusions. The device is not to be used in the carotid arteries.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Dan R. Vachney  
(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number K050916